ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

G.P.M.II, LLC; MLH EXPLORATIONS LLC; TRI-MOUNTAIN PURE, LLC; and STORY OF PA CR, LLC, *Petitioners*, v. DRUG ENFORCEMENT ADMINISTRATION; TERRANCE C. COLE, in his official capacity as ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION; UNITED STATES DEPARTMENT OF JUSTICE; and TODD BLANCHE, in his official capacity as UNITED STATES ATTORNEY GENERAL, *Respondents*.	No. 26-1325 Consolidated with Case No. 26-1324

REPLY IN SUPPORT OF EMERGENCY MOTION FOR STAY OF AGENCY ACTION PENDING REVIEW AND FOR IMMEDIATE ADMINISTRATIVE STAY

TABLE OF CONTENTS

INTRODUCTION 1
ARGUMENT 4
I. Petitioners Are Likely to Succeed on the Merits. 4
A. The Guidance Contravenes the Attorney General's Order and the Regulations It Promulgated. 4
B. The Guidance Undermines the Order's Findings and Objectives. 8
II. The Remaining Factors Favor Petitioners. 9
CONCLUSION 12
CERTIFICATE OF SERVICE 14

TABLE OF AUTHORITIES

Cases ..... **Page(s)**

Air All. Hous. v. EPA,
906 F.3d 1049 (D.C. Cir. 2018) 8

Encino Motorcars, LLC v. Navarro,
579 U.S. 211 (2016) 9

Statutes

21 U.S.C. §822(d) 2, 7

35 Pa. Stat. §10231.704(a) 6

Other Authorities

21 C.F.R. §1301.13 ..... 2, 3, 6, 7

90 Fed. Reg. 60,541, 60,542 (Dec. 18, 2025) §2 1

91 Fed. Reg. at 22,720 ..... *passim*

91 Fed. Reg. at 22,722 3

American Presidency Project, Remarks on Signing an Executive Order on Increasing Medical Marijuana and Cannabidiol Research and an Exchange With (Dec. 18, 2025), https://www.presidency.ucsb.edu/documents/remarks-signing-executive-order-increasing-medical-marijuana-and-cannabidiol-research-and 11

Executive Order 14370 1

INTRODUCTION

On December 18, 2025, President Trump issued Executive Order 14,370, instructing the Attorney General to "take all necessary steps to complete the rulemaking process related to rescheduling marijuana to Schedule III of the CSA."[1] He did so emphasizing that "Americans deserve access to the best medical treatments," and that HHS had for years advised DEA to move marijuana to Schedule III of the Controlled Substances Act due to "credible scientific support to substantiate the use of marijuana in the treatment of" debilitating medical conditions like chemotherapy-induced nausea and severe chronic pain. *Id.* §1. Four months later, the Attorney General placed "marijuana in any form covered by a state medical marijuana license" in Schedule III. 91 Fed. Reg. 22,714, 22,722 (Apr. 28, 2026) ("the Order"). The Order relied heavily on HHS's research and recommendation, *id.* at 22,717, and on the Attorney General's own determination that state medical-marijuana regimes "demonstrate a sustained capacity to achieve the public-interest objectives that underlie the CSA's registration framework, including protecting public health and safety and preventing the diversion of controlled substances into illicit channels," *id.* at 22,720.

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[1] *See* Exec. Order No. 14,370, Increasing Medical Marijuana and Cannabidiol Research, §2, 90 Fed. Reg. 60,541, 60,542 (Dec. 18, 2025) ("E.O.14370").

Yet this background does not appear in DEA's opposition to Petitioners' motion. Nowhere does DEA acknowledge the policy of this Administration or the Attorney General's "considered judgment" that "incorporating state licensing systems into the federal registration framework represents the most effective and efficient means of achieving the CSA's objectives," *id.* at 22,720. Instead, DEA urges, the relevant backdrop is the CSA's "closed system," Opp.3, under which an entity wishing to "engage in any activity for which registration is required" must be registered with DEA, 21 C.F.R. §1301.13(a). Opp.11-18.

DEA misses the mark. For one thing, the Attorney General waived the default registration requirement here, finding that waiver was "consistent with the public health and safety," 21 U.S.C. §822(d). Opp.8. But more to the point, waiver was consistent with the public health because state medical-marijuana licensing regimes *already* include "robust infrastructure for preventing diversion, ensuring product safety, [and] maintaining records." 91 Fed. Reg. at 22,720. That is why the Attorney General "incorporat[ed]" those regimes "into the federal registration framework," *id.*—a fact DEA has apparently overlooked.

In light of states' already-existing "comprehensive licensing frameworks," the Attorney General replaced the CSA's default registration scheme with "a new [federal] registration pathway for state-licensed medical marijuana entities." *Id.*; *see* 21 C.F.R. §1301.13(k) ("Medical marijuana registrations"). That pathway

authorizes applicants like Petitioners who "submit[ted] an application within 60 days" of the Order's publication to "continue to [operate] in conformity with a state-issued license during the pendency of the application." 21 C.F.R. §1301.13(k)(7). It does *not* limit early applicants to operating "as if they had a DEA registration 'during the pendency of [their] application,'" as DEA insists six times over. Opp.2, 8, 9, 12, 14-15; *see* 91 Fed. Reg. at 22,722. Rather, and to repeat, it states that early applicants may continue to engage in medical-marijuana activities "during the pendency of the[ir] application," so long as they operate "*in conformity with a state-issued license*." 21 C.F.R. §1301.13(k)(7) (emphasis added).

Petitioners seek nothing more. Each applied to register its dispensary facilities within 60 days of the Order's publication and appears on DEA's Timely Applicant list. Consistent with subparagraph (k)(7), Petitioners intended to operate in accordance with their Pennsylvania-issued licenses while their DEA applications are pending, including by sourcing medical marijuana from their own state-licensed manufacturing divisions. Mot.9-11. The Guidance would bar them from doing so—contrary to the Order and the regulations it established, and with devastating consequences for Petitioners' businesses and authorized patients across Pennsylvania. Mot.22-25.

Far from merely "summariz[ing] … pre-existing statutory and regulatory limits," Opp.4, the Guidance establishes new prohibitions, duties, and penalties that deviate from the regulations the Order promulgated and undermine the Order's findings and objectives. The Guidance thus constitutes an unlawful legislative rule, Mot.13-18, and arbitrary and capricious agency action, Mot.18-22. Because the remaining stay factors likewise favor Petitioners, the Court should grant the motion.

ARGUMENT

I. Petitioners Are Likely to Succeed on the Merits.

A. The Guidance Contravenes the Attorney General's Order and the Regulations It Promulgated.

DEA tries two responses to Petitioners' motion, but both boil down to the same argument: that the Guidance simply "summariz[es] the preexisting statutory and regulatory framework," Opp.14; *see* Opp.11-19 (outlining CSA's default registration requirements and contending that the Guidance "merely recounts these preexisting requirements"), 18-23 (asserting that Petitioners "challenge a letter with no legal effect and which is not the cause of their asserted injuries" because the Guidance "did nothing more than recount long-standing obligations"). DEA is wrong.

DEA's opposition, like its October 30 Guidance, reads as if written by someone who has never read the Attorney General's rescheduling Order. Indeed,

DEA appears entirely unaware that the Attorney General determined, after careful review of "robust" state medical-marijuana frameworks like Pennsylvania's, that adherence to existing state licensing systems "represents the most effective and efficient means of achieving the CSA's objectives," 91 Fed. Reg. at 22,720. Nor does DEA seem to apprehend that, for this reason, the Attorney General "incorporat[ed] state licensing systems *into the federal registration framework*," *id.* (emphasis added); *see also id.* (such "cooperative federalism best serves the statutory purposes of the CSA"). Petitioners do not seek to "buy and sell controlled substances without authorization under" federal law, Opp.1; they seek to operate exactly as the Attorney General contemplated and as the regulations promulgated by his Order direct: consistent with a federal framework that incorporates the "comprehensive" requirements of Pennsylvania's licensing system, 91 Fed. Reg. at 22,720.

Contrary to DEA's suggestion, then, Petitioners are nothing like "unregistered gas station[s]" or "backroom lab[s]," seeking to purchase prescriptions from authorized manufacturers or pharmacies. Opp.13. Rather, each Petitioner is a vertically integrated entity that timely registered its dispensary arm, and which seeks to supply its dispensaries from the manufacturing division of that same vertically integrated entity. Each Petitioner operates under a "well-regulated medical marijuana market" that has "demonstrate[d] a sustained capacity to

achieve the public-interest objectives that underlie the CSA's registration framework," 91 Fed. Reg. at 22,720. In fact, Pennsylvania's licensing regime is more exacting than the CSA's registration framework in multiple respects. *See* Mot.10 (comparing state and federal anti-diversion, record-retention, security, and tracking requirements); *see also* 35 Pa. Stat. §10231.704(a) (requiring independent, DOH-approved laboratory testing at harvest and final processing, which federal law does not require).

In light of these facts and the Attorney General's findings, it is no surprise that the Order established "a new [federal] registration pathway for state-licensed medical marijuana entities" premised on the dictates of state systems, 91 Fed. Reg. at 22,720; *see* 21 C.F.R. §1301.13(k). As explained, *see* Mot.3-4, 14-16, that pathway waives the CSA's usually applicable registration requirement and instructs that medical-marijuana applicants—like Petitioners—who apply for registration within 60 days of the Order's publication may continue to operate during the pendency of their applications "in conformity with a state-issued license." 21 C.F.R. §1301.13(k)(7). Subparagraph (k)(7), the only provision addressing applicants, does not say (as DEA asserts repeatedly) that such applicants may operate "as if they had a DEA registration 'during the pendency of [their] application,'" *e.g.*, Opp.2, 8, 9, 12, 14-15. It requires *state-law compliance*, and for good reason: the Attorney General concluded that that is the best "means of

achieving the CSA's objectives … while promoting the medical benefits of marijuana and causing the least disruption for patients and existing state systems." 91 Fed. Reg. at 22,720. Petitioners, in short, do not claim "greater right[s]" now as applicants than will be afforded when they are registrants, Opp.25; *see* Opp.15; they claim only the right to operate consistent with the Order and the regulations it established.

Yet the Guidance's counterparty restriction would prohibit Petitioners from doing so. DEA insists that the Guidance simply "summariz[es] the preexisting statutory and regulatory framework," Opp.14, but it summarizes the *wrong* statutory and regulatory framework—the CSA's default "closed" registrant-only system, Opp.3-5, 11-14, which the Attorney General waived here, Opp.8; 21 C.F.R. §1301.13(k)(7). It wholly ignores the *governing* statutory and regulatory framework, which is set forth in 21 U.S.C. §822(d) (permitting waiver of default registrant-only rule where, as here, waiver is "consistent with the public health and safety") and the Attorney General's Order and resulting regulations (establishing unique registration pathway premised on state medical-marijuana licensing regimes). The Guidance does not "merely recount" *those* provisions, Opp.14, or "simply … *inform* [petitioners] of" that framework, Opp.20 (citation omitted). Instead, as explained, it establishes new prohibitions, penalties, and obligations that contravene that framework. *See* Mot.14-17, 20-22. For these reasons, the

counterparty restriction constitutes final agency action, Mot.12, an unlawful legislative rule, Mot.13-18, and, because it contradicts the agency's regulations, arbitrary and capricious action that is "not in accordance with law," Mot.18-19.

B. The Guidance Undermines the Order's Findings and Objectives.

Given the foregoing, it is little wonder that DEA ignores Petitioners' argument that the Guidance is arbitrary and capricious because it contradicts the agency's prior findings without explanation. After all, DEA's opposition completely disregards the Attorney General's findings as to state medical-marijuana regimes, as well as his critical determination—to "incorporat[e] state licensing systems into the federal registration framework," 91 Fed. Reg. 22,720—that stems from those findings.

The Guidance does the same, in violation of the APA. It purports to cast aside the state-licensing systems the Order established as the backbone of federal registration for state medical-marijuana operators. And it invites the severe disruption to patients—and in turn, to "public health and safety"—that the Order expressly sought to avoid. Yet the Guidance fails to acknowledge these inconsistencies, let alone to adequately explain them. An agency must, however, "provide 'a reasoned explanation … for disregarding facts and circumstances that underlay [its] prior policy.'" *Air All. Hous. v. EPA*, 906 F.3d 1049, 1066 (D.C. Cir. 2018) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16

(2009)). Failure to do so is "reason for holding an interpretation to be an arbitrary and capricious change from agency practice." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) (citation omitted).

II. The Remaining Factors Favor Petitioners.

Petitioners showed that, absent a stay, they will experience catastrophic levels of operational disruption, with Petitioners' employees and the thousands of patients who rely on medical marijuana to treat chronic and debilitating health conditions bearing the cost. Mot.22-25. On the ledger's other side, DEA stands to lose nothing: a stay pending review would promote the very continuity for "patients and existing state systems" the Attorney General's Order sought to provide. 91 Fed. Reg. at 22,720.

DEA does not dispute the sea change that will result if the Guidance takes effect. Instead, it scoffs at the severe and irreparable harms Petitioners will face because, the agency asserts, they are problems of the Petitioners' "own making." Opp.24. And remarkably, DEA does not even acknowledge the impact the Guidance will have on the many patients across Pennsylvania who rely on Petitioners' products, suggesting that this harm, too, can be discounted.

The Government is wrong. First, far from "fail[ing] to adequately protect their interests by using" the process created by the Government "to come into compliance with federal law," Opp.24, the evidentiary record confirms that

Petitioners sought to do just that. Each registered its vertically integrated dispensary within 60 days of the Order's publication. And each waited to complete the generic manufacturer application form in anticipation of the medical-marijuana-specific manufacturer application DEA announced would be available within "weeks," Mot.6, and then failed to deliver within the 60-day window, Mot.7. Petitioners also called DEA's helpline to request guidance and asked DEA field agents how to proceed with respect to their manufacturer applications, and in each instance, DEA's agents advised Petitioners *not* to use the generic form and instead to wait for the medical-marijuana-specific application. Petitioners, in other words, had good reasons for awaiting the medical-marijuana application—reasons the government does not dispute. *See* Mot.6-7, 10-11; Waggoner Decl. ¶¶11, 15a; Reilly Decl. ¶18.

The Government next asserts that Petitioners' injury is not "irreparable" because it could simply grant Petitioners' applications, and "all … seemingly agree" that such action would prohibit Petitioners from transacting with Timely Applicants. Opp.25. DEA's own Guidance says otherwise. According to the agency, "Timely Applicants can … engage in schedule III medical marijuana activities with DEA registrants that hold a registration to handle schedule III medical marijuana." Ex.K ¶6; *see also* Opp.18 (early applicants may do business with "other early applicants or DEA registrants"). Under DEA's own account,

granting Petitioners' applications would have no effect on Petitioners' injury because Timely Applicants and registered entities are treated as one and the same.

DEA is also wrong to ignore the substantial harm to patients. As President Trump recognized when ordering the placement of medical marijuana on Schedule III, the countless patients who rely on medical marijuana do so to treat severe and debilitating conditions like "extreme pain, incurable diseases, aggressive cancers, seizure disorders, neurological problems, and more."[2] Absent access to Petitioners' products, thousands of patients, "who live with chronic medical problems" will see the quality of their lives "severely degrade." *Id.* Apparently, that doesn't trouble DEA.

Finally, in a last-ditch effort, the Government claims that a stay pending review would interfere with its ability to enforce the CSA, ensure public safety, and comply with its treaty obligations. Opp.26. Hardly. A stay would simply leave in place the "state licensing systems" the Attorney General has already determined "represent[] the most effective and efficient means of achieving the

[2] The American Presidency Project, Remarks on Signing an Executive Order on Increasing Medical Marijuana and Cannabidiol Research and an Exchange With Reporters (Dec. 18, 2025), https://www.presidency.ucsb.edu/documents/remarks-signing-executive-order-increasing-medical-marijuana-and-cannabidiol-research-and.

CSA's objectives," including "protecting the public health and safety and preventing the diversion of controlled substances." 91 Fed. Reg. at 22,720.

CONCLUSION

Petitioners respectfully request that the Court grant Petitioners' motion.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing reply complies with the word limit of Federal Rule of Appellate Procedure 27(d)(2)(C) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f), the reply contains 2,313 words. The reply complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 27(d)(1)(E) and 32(a)(5) and (6) because it has been prepared using Microsoft® Word for Microsoft 365 in proportionally spaced 14-point Times New Roman typeface. As permitted by Federal Rule of Appellate Procedure 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Beth C. Neitzel
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CERTIFICATE OF SERVICE

I, Beth C. Neitzel, certify that on November 24, 2026, I electronically filed the foregoing reply with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system.

/s/ Beth C. Neitzel
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